DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 30, 2015

Natec Medical, Ltd.
% Judith Danielson
Senior Regulatory Consultant
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 205
Baltimore, MD 21228

Re: K143036
Trade/Device Name: Ebony PTA 0.035 Peripheral Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: March 23, 2015
Received: March 25, 2015

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143036

Device Name
Ebony® PTA .035 Peripheral Dilatation Catheter

Indications for Use *(Describe)*
The Ebony® PTA .035 Peripheral Dilatation Catheter is intended for dilatation of lesions in the femoral, iliac, popliteal, infrapopliteal & renal arteries.
The Ebony® PTA .035'' OTW Peripheral Dilatation Catheter is not for use in the coronary arteries and neuro-vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Ebony® PTA 0.035'' Peripheral Dilatation Catheter
510(k) SUMMARY
21 CFR 807.92

Applicant:

Company Name:	Natec Medical Ltd.
Company Address:	Maeva Centre Building - Ebene Business Park Reduit, Mauritius
Telephone:	+230 466 30 54
Fax:	+230 466 67 70
Contact Person:	Xavier De Buchere Regulatory Affairs & Quality Manager xdbuchere@natec-medical.com

Summary Preparation Date: October 14th, 2014

Device Name:

Trade Name:	Ebony® PTA 0.035 Peripheral Dilatation Catheter
Common/Usual Name:	PTA Catheter
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR 870.1250
Product Code:	LIT
Device Class:	Class II

Predicate Devices:

- Ebony® PTA 0.035 Peripheral Dilatation Catheter (K103354)

Device Description:

The Ebony® PTA 0.035 Peripheral Dilatation Catheter is a standard Over The Wire (OTW) PTA catheter with a semi-compliant inflatable balloon at the distal part with an atraumatic, tapered tip at its distal end. Two radiopaque markers facilitate proper balloon positioning across the stenosis, and a hydrophilic coating facilitates advancement of the catheter through the vasculature.

The modified Ebony® PTA 0.035 Peripheral Dilatation Catheter line extension adds 3.0 mm and 4.0 mm diameter balloon and additional balloon lengths to the currently available sizes.

Indication for Use:

Ebony® PTA 0.035 Peripheral Dilatation Catheter is intended for dilatation of lesions in the femoral, iliac, popliteal, infra popliteal and renal arteries.
The Ebony® PTA .035'' OTW Catheter is not for use in the coronary arteries and neuro-vasculature.

Technological Characteristics:

The modified Ebony® PTA 0.035 Peripheral Dilatation Catheter has the same indication for use, and is manufactured with the same over the wire design and materials as the Ebony® PTA 0.035 Peripheral Dilatation Catheter cleared under K103354. The modification involved adding balloon diameter 3.0mm and 4.0mm and longer balloon lengths (100, 120, 150 and 200 mm) to the previously cleared balloon size matrix and a change in the hydrophilic coating material.

Non-Clinical Testing Summary:

The following bench testing was performed according to the same testing method used with the original Traditional 510(k) cleared under K103354.

- Balloon compliance
- Balloon burst pressure
- Balloon fatigue
- Biocompatibility testing (A summary of biocompatibility results is provided in file 002).
- Shaft resistance (Torque Test)
- Bond strength
- Catheter dimensions
- Coating integrity (Visual inspection)
- Deflation time
- Guide wire and introducer compatibility.

Clinical Testing Summary:

No clinical study was performed.

Conclusion

The proposed device and the predicate Ebony® PTA 0.035 Peripheral Dilatation Catheter (K103354) have the same indication, similar materials and a similar design. The new balloon sizes met all of the verification/validation acceptance criteria and the biocompatibility results demonstrated that the modified Ebony® PTA 0.035 Peripheral Dilatation Catheter is substantially equivalent to the predicate device.